

COMMONWEALTH of VIRGINIA

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To: Virginia Emergency Medical Services Agencies

Regional Emergency Medical Services Councils

Operational Medical Directors

From: Michael D. Berg

Manager, Regulation and Compliance

SUBJECT: Electronic signatures for prescribed drugs

On March 31, 2010, the Drug Enforcement Administration (DEA) published in the Federal Register an Interim Final Rule with Request for Comment entitled "Electronic Prescriptions for Controlled Substances" (75 FR 16236) [Docket No. DEA-218, RIN 1117-AA16]. The rule becomes effective June 1, 2010. The regulations permit pharmacies, hospitals and practioners to use modern technology for controlled substance prescriptions while maintaining the closed system on controlled substances.

What does this mean for the Virginia EMS System?

The use of electronic signatures on patient care reports and other documents must meet the new DEA requirements for security and validation as prescribed in the Final Rule (http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/eapplications.htm). The routine use of electronic signatures of the "authorized Practioner" as defined in the Virginia Emergency Medical Services Regulations 12 VAC5-31-1140 on the various applications and devices used in the field setting (electronic tablets, etc) must be certified by a recognized third party to comply with the new DEA standards and criteria.

Additionally, DEA's Interim Final Rule does not permit a form containing the electronic signature of a prescriber to be printed and delivered or faxed to the pharmacy in order to exchange a drug kit. An order or prescription for a Schedule II – V drug bearing the prescriber's electronic signature must be sent as an electronic file directly to the pharmacy. Therefore, effective June 1, 2010, the "authorized Practioner" (or also referred to as the "prescriber") must manually sign a paper document for the drug box/drug exchange until the electronic application/device utilized by your agency can be certified by an authorized third party.

Lastly, the Drug Control Act does not allow an Operational Medical Director (OMD) to authorize the administration of drugs by "protocol/standing orders." Therefore, the current regulation that requires the signature on the prehospital patient care report of the medical practitioner who assumes responsibility for the patient when a drug is administered as defined in 12VAC5-31-1140 must be followed and cannot be changed at this time.

